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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,109	01/11/2005	Francesco Tedesco	50294/016001	5428

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CLARK & ELBING LLP
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BOSTON, MA 02110

EXAMINER

VANDERVEGT, FRANCOIS P

ART UNIT	PAPER NUMBER
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1644

NOTIFICATION DATE	DELIVERY MODE
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11/21/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary

Application No.

10/521,109

Applicant(s)

TEDESCO ET AL.

Examiner

F. Pierre VanderVegt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-76 is/are pending in the application.
- 4a) Of the above claim(s) 50-55, 57 and 59-76 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 37 is/are allowed.
- 6) ☒ Claim(s) 38, 41-48, 56 and 58 is/are rejected.
- 7) ☒ Claim(s) 39, 40 and 49 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This application is a Rule 371 continuation of PCT Serial Number PCT/EP03/078487.

Original claims 1-36 have been canceled.

Claims 37-76 are currently pending.

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 37-49, 56, and 58, in the reply filed on September 5, 2007 is acknowledged. The traversal is on the ground(s) that the restriction requirement in a 371 application is improper and the cited reference by Fitch teaches humanized, not human, antibodies that are not disclosed as being able to bind the region 731-740 of human C5. This is not found persuasive because the antibody of claim 56 is not limited to being a human antibody. Furthermore, the claim is written in an open format, requiring the C5 molecule to comprise the sequence 731-740 of human C5, but not requiring the antibody to bind specifically to that portion of the molecule. Accordingly, Fitch satisfies the metes and bounds of the claim and there is no unity of invention. Also, the claim set presented for national stage prosecution is not the same claim set presented for international search purposes.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 50-55, 57, and 59-76 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on September 5, 2007.

Claim Objections

3. Claims 38-49 are objected to because of the following informalities:

Claims 38-49 lack an article and do not read as a complete sentence. The claims should each be amended to recite --A--, --An-- or --The-- at the beginning of the claim as appropriate.

Appropriate correction is required.

Claim Rejections - 35 USC § 112 & 35 USC § 101

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claim 38, 41-48 and 58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 38 recites the limitation "said C5 component is...mouse, rat (or) rabbit." There is insufficient antecedent basis for this limitation in the claim. Claim 37 limits the peptide in the recitation of "said peptide having the sequence KDMQLGRLHMKTLTPVSK (SEQ ID NO: 15)," which is a human C5 sequence not exactly matched in the mouse, rat and rabbit C5 molecules. Accordingly, the recitation of mouse, rat and rabbit in claim 38 is not supported by base claim 37.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, **claim 41** recites the broad recitations "lambda chain," "kappa chain" and "VH3 region," and the claim also recites "V λ 3/V2-14," "V κ 4/DPK24" and "VH3/V-48" which are the narrower statements of the range/limitation.

Claim 58 provides for the use of the composition of claim 56, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 58 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 56 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Fitch (Circulation [1999] 100:2499-2506; cited on form PTO-1449).

Fitch teaches a pharmaceutical composition comprising the humanized form of the antibody 5G1.1, which blocks the conversion of activated human C5 to C5a and C5b (see entire reference). The claim is drafted in an open format, in that the target C5 polypeptide “comprises” the KDMQLGRLHMKTLTPVSK sequence of human C5. The claim does not require that the antibody binds to the recited sequence, only that the antibody binds to a polypeptide comprising the sequence. Accordingly, any antibody that binds to human C5 and inhibits C5 conversion to C5a and C5b satisfies the metes and bounds of the claim. The prior art teaching anticipates the claimed invention.

Conclusion

6. Claim 37 is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

F. Pierre VanderVegt, Ph.D. /PV/
Patent Examiner
November 13, 2007

A handwritten signature in cursive script that reads "David A. Saunders".

DAVID A. SAUNDERS
PRIMARY EXAMINER